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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,907	10/17/2003	Piero Del Soldato	026220-00039	7509
4372	7590	01/17/2007	EXAMINER	
ARENT FOX PLLC			CHONG, YONG SOO	
1050 CONNECTICUT AVENUE, N.W.				
SUITE 400			ART UNIT	
WASHINGTON, DC 20036			PAPER NUMBER	
			1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/17/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/686,907

Applicant(s)

DEL SOLDATO ET AL.

Examiner

Yong S. Chong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-6 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 5-6 (in part) are drawn to a method for the treatment of gastrointestinal tumors by administering a compound where  $X = O$  and R is chosen from Group IA, classified in 514/506.
- II. Claims 1 (in part), 2-3, 5-6 (in part) are drawn to a method for the treatment of gastrointestinal tumors by administering a compound where  $X = O$  and R is chosen from Group IIA, classified in 514/510.
- III. Claims 1, 5-6 (in part) are drawn to a method for the treatment of gastrointestinal tumors by administering a compound where  $X = O$  and R is chosen from Group IIIA, classified in 514/506.
- IV. Claims 1, 5-6 (in part) are drawn to a method for the treatment of gastrointestinal tumors by administering a compound where  $X = O$  and R is chosen from subgroup IVA, classified in 514/510.
- V. Claims 1, 5-6 (in part) are drawn to a method for the treatment of gastrointestinal tumors by administering a compound where  $X = O$  and R is chosen from subgroup VA, classified in 514/506.
- VI. Claims 1 (in part), 2, 4, 5-6 (in part) are drawn to a method for the treatment of gastrointestinal tumors by administering a compound where  $X = O$  and R is chosen from subgroup VIA, classified in 514/510.
- VII. Claims 1, 5-6 (in part) are drawn to a method for the treatment of gastrointestinal tumors by administering a compound where  $X = NH$  or  $NR1c$  and R is chosen from subgroup IA, classified in 514/675.
- VIII. Claims 1 (in part), 2-3, 5-6 (in part) are drawn to a method for the treatment of gastrointestinal tumors by administering a compound where  $X = NH$  or  $NR1c$  and R is chosen from subgroup IIA, classified in 514/676.
- IX. Claims 1, 5-6 (in part) are drawn to a method for the treatment of gastrointestinal tumors by administering a compound where  $X = NH$  or  $NR1c$  and R is chosen from subgroup IIIA, classified in 514/678.

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- X. Claims 1, 5-6 (in part) are drawn to a method for the treatment of gastrointestinal tumors by administering a compound where X = NH or NR1c and R is chosen from subgroup IVA, classified in 514/675.
- XI. Claims 1, 5-6 (in part) are drawn to a method for the treatment of gastrointestinal tumors by administering a compound where X = NH or NR1c and R is chosen from subgroup VA, classified in 514/676.
- XII. Claims 1 (in part), 2, 4, 5-6 (in part) are drawn to a method for the treatment of gastrointestinal tumors by administering a compound where X = NH or NR1c and R is chosen from subgroup VIA, classified in 514/678.

*Note: Each of the above Groups (I-XII) further contains separate R subgroup set as listed below so as to form a separate invention. Applicant is required to select one of the following subgroups according to the elected Group. For example a proper elected for Group X would be X-Ia*

subgroup IA: IAa or IAb

subgroup IIA: II, XXI, IV, VII, XXXV, VI, VIII, IX, X, III, IIIa, XXX, XXXI, XXXII, XXXIII, XXXVI, or XXXVII

subgroup IIIA: II, X, or III

subgroup IVA: IV

subgroup VA: V Aa1, V Aa2, V Aa3, V Aa4, V Aa5, V Ab1, V Ac1, V Ac2, V Ac3, V Ac4, V Ac5, V Ad1, V Ad2, V Ad3, V Ad4, V Ae1, V Ae2, V Ae3, V Ae4, V Ae5, V Ae6, V Ae7, V Ae8, V Ae9, V Ae10, V Ae11, or V Ae12

subgroup VIA: Ia or Ib

The inventions are distinct, each from the other because of the following reasons:

Inventions I-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of the compounds of formula in claim 1

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containing subgroups IA-VIA are totally different compounds. They have different structures, thus leading to different reactivity, binding affinity, mechanism, stability, polarity, bioavailability, efficacy, solubility, and modes of action. Furthermore, the search for one will not lead to information regarding another, and vice versa. Because these inventions are distinct for the reasons given above and the search required for one invention is not required for another, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

### ***Species Election***

This application contains claims directed to more than one species of the generic invention.

The species are as follows:

1) a single disclosed compound of the formula in claim 1, for example the first compound according to claim 5

If applicant elects Invention I-XII, applicant is further required to elect a single disclosed compound of the formula in claim 1 from subsection 1. Currently, claims 1-6 are generic to a plurality of disclosed patentably distinct species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Note the court in *In re Herrick et al.* and *In re Joyce et al.* (both at 115 USPQ 412) held that an election of species requirement was, in fact, a restriction requirement.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call to the attorney is not required where: 1) the restriction requirement is complex, 2) the application is being prosecuted pro se, or 3) the examiner knows from past experience that a telephone election will not be made (MPEP

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§ 812.01). Therefore, since this restriction requirement is considered complex, a call to the attorney for telephone election was not made.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

  
SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER